Instructions for use

MACH LED 120F / 120

Mach LED 120F / 120 mobile lights – with short arm
Mach LED 120F / 120 mobile lights - SWING
Mach LED 120F / 120 wall lights
Mach LED 120F / 120 ceiling lights

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Dear customer!

Congratulations for acquiring our new OT-light **MACH LED 120F / LED 120**.

The new OT-light generation with LED technology supports your professionalism by innovative technology and design.

The advantages of the LED technology: a life-span of minimum 40.000 hours and an almost nonexistent heat development in the surgeon's head area and in the wound field.

The advantages already provided by Dr. Mach's light technology with halogen and gas discharge lamps have been maintained: natural color reproduction, exact illumination of the wound field and easy positioning of the light head.

1. Safety instructions

Pay attention to the instructions for use when handling the lamp.

WARNING:

This device has not been designed for use in potentially explosive areas.
According to the Medical Device Regulation the light is classified under class I.

Store the OT-light in its package for at least 24 hours in the respective room before mounting, in order to equal temperature differences.

Please read the instructions for use carefully to make the most of your lighting system and to avoid any damages to the device.

The lights may only be repaired and special assembly work may only be carried out on the reflector or sockets by ourselves or a company that has been expressly authorized by us.

The manufacturer can only be made responsible for the safety of the light if repairs and alterations are carried out by the manufacturer himself or a company that guarantees to observe the safety regulations.

The manufacturer cannot be made liable for personal or material damages if the light is operated inexpediently or incorrectly or used for purposes other than those for which it is intended.

The light is to be dismantled from the spring arm in reverse order to its assembly. This may only be carried out after the spring arm has been adjusted in height at horizontal position since the arm is under spring tension and can bounce up.

Make sure that the light is in perfect working order before every use.

Attention, external power supply!
The light works only with an external power supply.
The external power supply used with the OT-light must be tested and validated according to IEC 60601-1.

Attention!
A main control switch must be installed for turning the system power-off.

ATTENTION!
During the mounting of the OT-lights the entire system (incl. the ceiling attachment) must be disconnected from mains! A later dismounting of the lights from the spring arms or dismounting the sliding contacts inside the arms is to be done ONLY AFTER DISCONNECTING THE ENTIRE SYSTEM FROM MAINS. Otherwise the electronic board will be damaged!

Symbols and notes used in this user manual:

This symbol means possible hazard sources. Please observe also the safety remarks and the hazard specifications mentioned in the mounting instructions and user manuals from Ondal company.

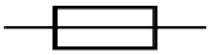
This symbol means possible hazard caused by electric current. Please observe also the safety remarks and the hazard specifications mentioned in the mounting instructions and user manuals from Ondal company.

This symbol refers to important mounting indications, useful information and operation hints.

This symbol indicates to observe the user manual.

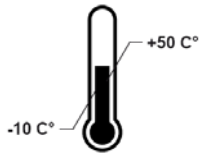
Alternating current

Bulb



Fuse

Indication on China RoHS / Pollution control Logo China



Temperature range for transport and storage

Indication for disposal

2. Brief description of the light MACH LED 120F / LED 120

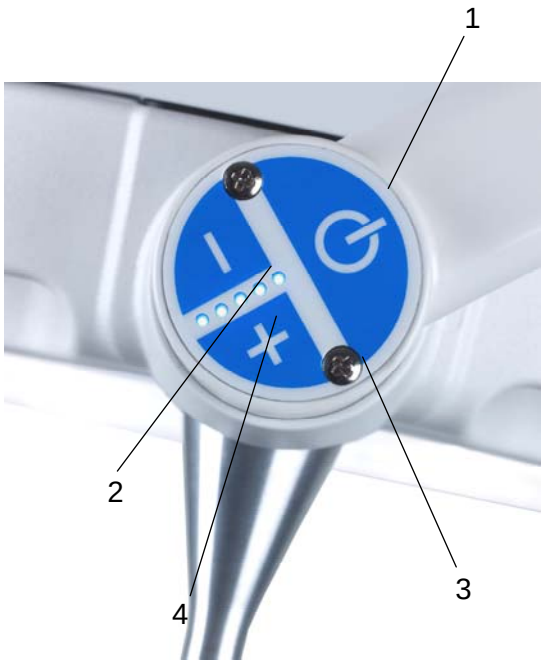
Intended use of the light Mach LED 120F / LED 120:

- The light is used for treatment, diagnosis and in operating theatres.
- The light is used in medical rooms (groups 0, 1 and 2 according to DIN VDE 0100-710).
- The light is mounted to the ceiling, wall or on mobile stand.
- Maintenance of the light must be scheduled every 2 years.
- The light has a fixed electrical connection.

The OT-light MACH LED 120 is available in following versions:

- Mach LED 120F with focusing function and light intensity control
- Mach LED 120 (fixed focus) with light intensity control

3. Operating the light MACH LED 120F / LED 120



3.1. ON/OFF switch

The push button **1** on the control panel turns the light **MACH LED 120F / LED 120** ON and OFF.

3.2. Light intensity control

The lights Mach LED 120F / LED 120 offer the facility of light intensity control.
The adjustment range of the light intensity is from 50 % to 100 %.
The light intensity can be adjusted according to the requirements of the surgeon / physician.

The light intensity can be decreased by pressing push button **2**.
The light intensity can be increased by pressing push button **3**.

The set light intensity is shown by the display **4**.

3.3. Focusing (Mach LED 120F only)

The lamp-models Mach LED 120F have a focusing function. That means, you can either enlarge the diameter of the light field or bundle the light to a smaller area, depending on the circumstances.

To activate the function of focusing turn the handle **5** (see figure).

3.4. Positioning

Use the handle **5/6** or the handle rail **7** to position the lamp.

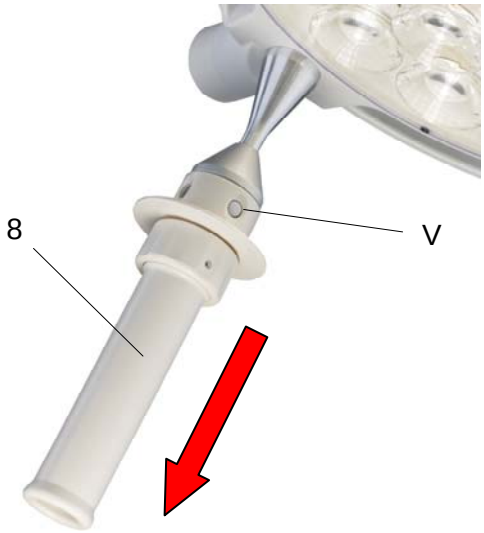
Use the handle rail to position the lights before the operation.

Use the handle for positioning the light during the operation.

There are two handle-types available:

- Standard handle **5**
- Sterilisable handle **6** (against surcharge)
  The sterilisable handle can be removed for sterilisation.

4. Cleaning



4.1. Sterilisable handle

The light can be equipped against surcharge with the **sterilisable handle 8**. The handle sleeve is removable and sterilisable. Before using the first time and before every use the handle sleeve must be cleaned, disinfected and sterilised.

The handle sleeve must be removed for sterilization:

- To remove press the lock **V** and pull off the sterilisable handle sleeve **8** while keeping the lock pressed.
- To attach, push on and slightly twist the handle until the lock **V** engages securely.

Handles often become unsterile during an operation. Therefore always keep additional handles available for exchange.

Cleaning / disinfection and sterilization

Basics
Efficient cleaning / disinfection is an essential requirement for effective sterilization of the handle.
Within the scope of responsibility for the sterility of the products it should be noted that only sufficiently validated equipment and product specific processes are used for cleaning / disinfection and that the validated parameters are complied with in every cycle.
In addition, the hospital / clinic hygiene regulations must be observed.

Cleaning / disinfection
Cleaning and disinfection must be carried out immediately after use.
A mechanised process (disinfector) should be used for cleaning / disinfection. The efficiency of the process used must be recognized and validated in principle (e.g. listed under disinfectants and disinfection procedures tested and recognized by Robert-Koch-Institute / DGHM).
When using other procedures (e.g. a manual procedure), proof and process efficiency in principle must be provided within the scope of validation.
Proof in principle of the suitability of the handles for efficient cleaning / disinfection was provided using a cyclic cleaning system (Netsch-Bellmed T-600-IUDT/AN, programme 2 for small parts; code B).

It is not allowed to use agents / disinfectants, which contain the following substances, as these may cause changes in the material:

- High-concentration organic and inorganic acids
- Chlorinated hydrocarbons
- 2-ethoxyethanol

When cleaning / disinfecting, the following procedures must be followed**:**

	Process	Time (sec.)
Zone 1	Pre-rinse, external, cold, 10 – 15°C Washing, acidic, external 35°C Draining time Re-rinse, external approx. 80°C Draining time Re-rinse, external approx. 80°C Draining time	45 120 10 *10 *15 *15 15
Zone 2	Washing, alkaline, external, 93°C Draining time Re-rinse, external, acidic, 90°C Draining time Re-rinse, external 90°C Draining time	135 10 10 15 15 15
Zone 3	Drying, external 100 – 120°C	200
Zone 4	Drying, external 100 – 120°C	200
	Door open / close & transport (sluice discharge)	60
	Cycle time overall ca.	290 ≈ 5 minutes

* When occupying the disinfection zone (washing zone 2), the re-rinse and draining times will depend on the respective objects being washed therein!

Sterilization

Only previously cleaned and disinfected handles may be sterilised.
The handles are placed in a suitable sterilization pack (one-way sterilisation pack, e.g. foil / paper sterilization bags, single or double pack) in accordance with DIN EN 868 / ISO 11607 for steam sterilization and then sterilised.
Use only the sterilization procedure listed below for sterilization. Other sterilization procedures (e.g. ethylene oxide, formaldehyde and low-temperature plasma sterilization) are not permissible.

Steam sterilization procedure
Validated in accordance with DIN EN 554/ISO 11134
Maximum sterilization temperature 134°C

Proof in principle of the handles' suitability for effective sterilization was provided using a fractional vacuum process (Euroselectomat 666 by MMM Münchner Medizin Mechanik GmbH, sterilising temperature 134°C, holding time 7 min.)

Inspection / durability

The handles should be inspected for damage and changed before re-use, if required.
The handles may be cleaned / disinfected, sterilised and re-used for a maximum of 1000 times. If the handles are re-used more than 1000 times, then this will be the responsibility of the hospital / clinic.

4.2. Lamp housing, protective lens and support system

The Dr. Mach OT-lamp system has a high-quality surface, which can be cleaned with conventional cleaning agents.

The lens system **9** is made of a high-quality plastic. Pay attention to the following during cleaning:

- Never wipe over the lens system **9** with a dry cloth (always clean with a wet cloth).
- Only use disinfectants with **less than 20% alcohol**.

Alc. ≤ 20 %

Wipe the lens system **9** after cleaning with an anti-static, non-fluffy cloth.

5. Maintenance

Preventive maintenance of the light should be done every two years. This includes a technical and mechanical check-up.
Please observe also the manufacturer's mounting instructions for the ceiling and wall attachment.

In order to keep the system easy-running throughout its life span, we recommend that the hinges should be greased once a year with acid-free grease.

Attention:
Set the height adjustment, if applicable, of the spring arm to horizontal position before dismounting the lamp, (Please observe also the manufacturer's mounting instructions for the ceiling and wall attachment).

Attention: During all maintenance work the light must be disconnected from mains and secured against resetting.

5.1. Periodical maintenance work

The following maintenance work / tests has / have to be done every six months:
- check on defects in paint work;
- check on fissures at plastic parts;
- check on deformation of the suspension.

The following maintenance work / tests has / have to be done once a year:
- check the function;
- electrical safety test;
- check the suspension.

Check and grease the security segment once a year.

For adjustments at the ceiling attachment please observe also the mounting instructions **„Acrobat Swing ceiling attachment"**.

6. Data

6.1. Technical data

	Mach LED 120F	Mach LED 120
Central light intensity at a distance of 1 meter	40.000 Lux	30.000 Lux
Colour rendering index R_a	95	95
Focusable light field size	14-25 cm	17 cm (fixed focus)
Colour temperature (Kelvin)	4500 K	4500 K
Electronic light intensity control at the light head	50 – 100 %	50 – 100 %
Temperature increase in head area	0,5 °C	0,5 °C
Number of LED's	12	12
Working distance	70-140 cm	70-140 cm
Diameter of the light head	29 cm	29 cm
Height adjustment	121 cm	121 cm

Remark:
The technical data are subject to fluctuations. Due to manufacturing reasons the real values can slightly differ from the data mentioned above.
The values for R_a and R_9 can differ with approx ± 5%.
The values for the colour temperature can differ with approx ± 200K.

6.2. Electrical Data

	Mach LED 120F / 120
Power consumption	18 W
Operating voltage DC	24 V DC
Current	0,75 A

6.3. Environmental conditions

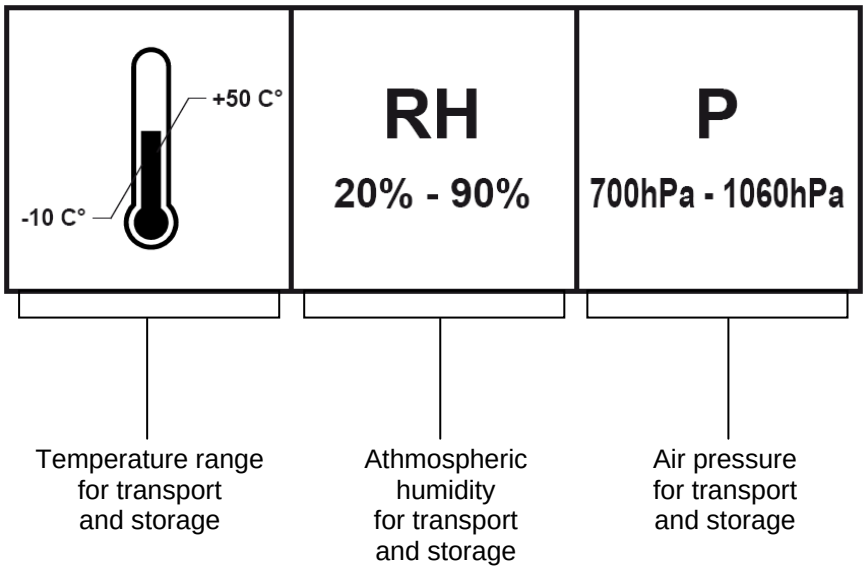
Operation

	Min.	Max.
Temperature	+10°C	+40°C
Relative atmospheric humidity	30 %	75 %
Air pressure	700 hPa	1060 hPa

Transport / storage

	Min.	Max.
Temperature	-10°C	+50°C
Relative atmospheric humidity	20 %	90 %
Air pressure	700 hPa	1060 hPa

References on the package



6.4. General remarks

When using more than one OT-lamp at the same time (OT-lamp combinations), please make sure that the total radiation intensity in field is less than 1000 W/m^2, to avoid further temperature increase in the wound field.

Due to the light fields overlapping of different lights the maximum permissible values according to EN 60601-2-41 for UV-radiation (< 400 nm) of 10 W/m² can be exceeded.

When installing an OT-lamp, its fail-safety must be guaranteed according to DIN VDE 0100-710 (former DIN VDE 0107)

Attention!
The test certificate for the electrical safety test can be requested when needed. Please provide the serial number of the respective light.

The light must still be tested at commissioning.

Protective conductor

Alternating current

The polarity is very important for the installation of the light. In case the light does not function after installation, the polarity must be checked at the secondary side of the power supply.

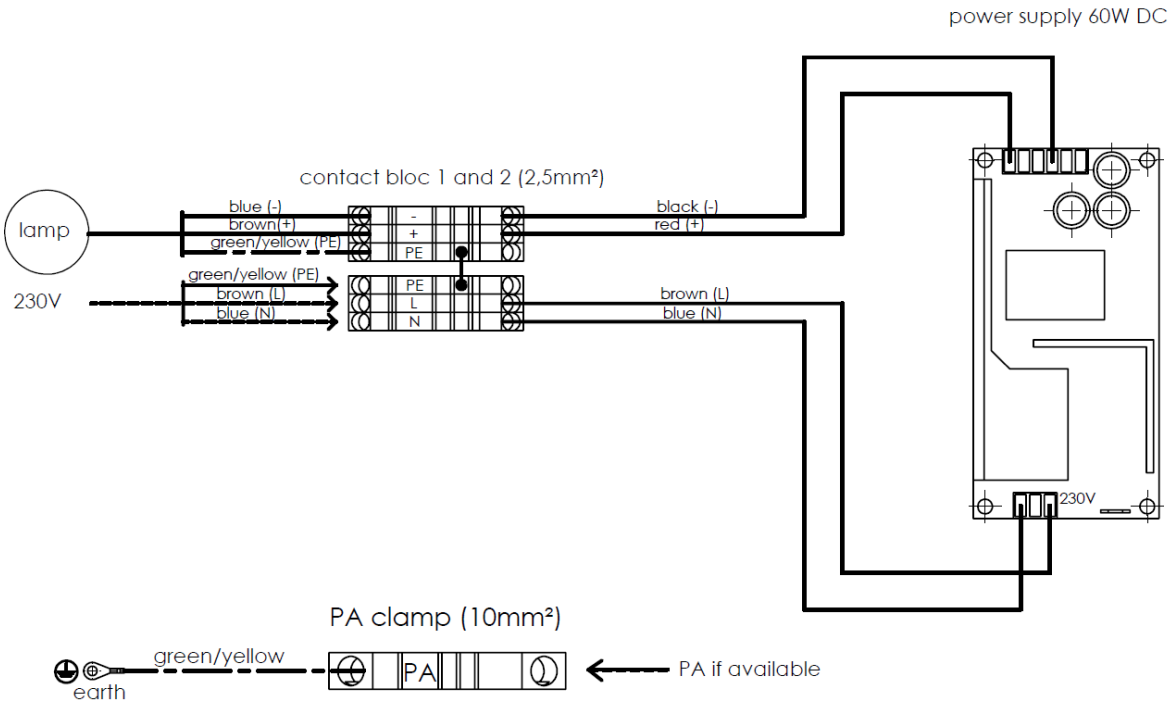
7. CE-mark

The products Mach LED 120F / LED 120 comply with the standards 93/42/EEC for medical products of the European Community's Council. Dr. Mach applies the standard EN 60601-2-41.
Dr. Mach GmbH is certified according to DIN EN ISO 13485:2003 + AC:2009.

8. Disposal

The OT-lamp doesn't contain any dangerous goods.
The components of the OT-lamp should be properly disposed at the end of its shelf-life.
Make sure, that the materials are carefully separated.
The electrical conducting boards should be submitted to an appropriate recycling proceeding.
The rest of the components should be disposed according to the contained materials.

9. Wiring diagram



10. Electromagnetic compatibility

The Dr. Mach OT- and examination lights are subject to special preventive measures regarding the electromagnetic compatibility and must be installed according to the EMC-instructions mentioned in the accompanying documents.

The function of the OT- and examination lights can be affected by portable and mobile HF-communication devices.

Table 1 – Guidance and manufacturer´s declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS (see 5.2.2.1 c)

1	**Guidance and manufacturer´s declaration – electromagnetic emission**		
2	The MACH LED 120F / LED 120 0 is intended for use in the electromagnetic environment specified below. The customer or the user of the MACH LED 120F / LED 120 should assure that it is used in such an environment.		
3	**Emissions test**	Compliance	Electromagnetic environment - guidance
7	Harmonic emissions IEC 61000-3-2	Class C	The MACH LED 120F / LED 120 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
8	Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	
12	RF emissions CISPR 15	Complies	The MACH LED 120F / LED 120 is not suitable for interconnection with other equipment.

Table 2 – Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS (see 5.2.2.1 f)

Guidance and manufacturer´s declaration – electromagnetic immunity			
The MACH LED 120F / LED 120 is intended for use in the electromagnetic environment specified below. The customer or the user of the MACH LED120F / LED 120 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 sec	< 5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MACH LED 120F / LED 120 requires continued operation during power mains interruptions, it is recommended that the MACH LED 120F / LED 120 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a. c. mains voltage prior to application of the test level.			

Table 4 – Guidance and manufacturer´s declaration – electromagnetic immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING (see 5.2.2.2)

Guidance and manufacturer´s declaration – electromagnetic immunity			
The MACH LED 120F / LED 120 is intended for use in the electromagnetic environment specified below. The customer or the user of the MACH LED 120F / LED 120 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 V 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the MACH LED 120F / LED 120 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}17\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}34\sqrt{P}$ 800 MHz to 2,5 GHz where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MACH LED 120F / LED 120 is used exceeds the applicable RF compliance level above, the MACH LED 120F / LED 120 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MACH LED 120F / LED 120.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 6 – Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING (see 5.2.2.2)

Recommended separation distances between portable and mobile RF communications equipment and the MACH LED 120F / LED 120			
The MACH LED 120F / LED 120 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MACH LED 120F / LED 120 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MACH LED 120F / LED 120 as recommended below, according to the maximum output power of the communications equipment			
	Separation distance according to frequency of transmitter m		
Rated maximum output of transmitter W	150 kHz to 80 MHz $d = 1{,}17\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}17\sqrt{P}$	800 MHz to 2,5 GHz $d = 2{,}34\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,69	3,69	7,38
100	11,67	11,67	23,33
For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			